XI. Summary of Proposed Changes for 2002

A. Changes Required by BIPA 2000

We are proposing the following changes to the OPPS, to implement the provisions of BIPA 2000:

- Limit coinsurance to a specified percentage of APC payment amounts.
- Provide hold-harmless transitional corridor payments to children's hospitals.
- Provide separate APCs for services that use contrast agents and those that do not.
- Pay for glaucoma screening as a covered service.
- Pay for certain new technology used in screening and diagnostic mammograms.

B. Additional Changes

We are proposing the following additional changes to the OPPS:

- Add APCs, delete APCs, and modify the composition of services within some existing APCs.
- Add an APC group that would provide payment for observation services in limited circumstances to patients having specific diagnoses.
- Recalibrate the relative payment weights of the APCs.

- Update the conversion factor and wage index.
- Revise the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights and the other required updates and adjustments.
- Make reductions in pass-through payments for specific drugs and categories of devices to account for the drug and device costs that are included in the APC payment for associated procedures and services.
- Apply a standard procedure to calculate copayment amounts when new APCs are created or when APC payment rates are increased or decreased as a result of recalibrated weights.
- Calculate outlier payments on a service-by-service basis beginning in 2002. We also propose a methodology for allocating packaged services to individual APCs in determining costs of a service and we propose to use a hospital's overall outpatient cost-to-charge ratio to convert charges to costs.
- Change the threshold for outlier payments to require costs to exceed 3 times the APC payment amount, and pay 50 percent of any excess costs above the threshold as an outlier payment.

- Exclude hospitals located outside the 50 states, the District of Columbia and Puerto Rico from the OPPS.
- Exclude from payment under the OPPS certain services that are furnished to inpatients of hospitals that do not submit claims for outpatient services under Medicare Part B.
- Exclude from the OPPS certain items and services (for example, bad debts, direct medical education and certain certified registered nurse anesthetists services) that are paid on a cost basis.
- Propose to update the payments for pass-through radiopharmaceuticals, drugs, and biologicals on a calendar year basis to reflect increases in AWP.
- Allow reprocessed single use devices to be considered eligible for pass-through payments if the reprocessing process for single use devices meets the FDA's most recent criteria.
- Revise the criteria we will use to determine whether a procedure or service is eligible to be assigned to a new technology APC.
- Revise the list of information that must be submitted to request assignment of a service or procedure to a new technology APC.

- Provide more flexibility in the amount of time a service may be paid under a new technology APC.

C. Technical Corrections

We are proposing to make conforming changes to the regulations in 42 CFR parts 413, 419 and 489.

In part 413 we would--

- Revise § 413.24(d)(6) and (d) (7) to clarify requirements for adequate cost data and cost findings and clarify the meaning of the paragraph.

- Revise § 413.65(a)(1) to clarify the specified types of facilities identified in this section that are not subject to the provider-based requirements and that provider-based determinations will not be made for them.

- Revise the definition of "Provider-based entity" in § 413.65(a)(2).

- Revise § 413.65(b) to implement the BIPA provisions on grandfathering and temporary treatment of a facility as provider-based.

- Delete the existing requirement in § 413.65(c)(1) in order to prevent unnecessary duplicate reporting.

- Specify in § 413.65(d)(7) that a facility will meet provider-based geographic location criteria if it and the main provider are located on the same campus, or if a

facility meets one of the three criteria specified in this paragraph.

- Clarify in § 413.65(g)(7) that the hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

- Correct date references in §§ 413.65(i)(1)(ii) and (i)(2), in order to take into account the effective date of the current regulations.

In part 419, we would --

- Revise § 419.2 to clarify the costs that are excluded from the OPPS rates.

- Revise the reference to the effective date of the OPPS to August 1, 2000 in § 419.20(a).

- Add new §§ 419.20(b)(3) and (b)(4) to specify that a hospital located outside one of the 50 States, the District of Columbia, or Puerto Rico, or a hospital of the Indian Health Service is excluded from the hospital outpatient prospective payment system.

- Add a new § 419.22(r) to specify that services defined in § 419.21(b) that are furnished to inpatients of hospitals that do not submit claims for outpatients

services under Medicare Part B are not paid for under the hospital OPPS.

- Revise § 419.32 to reflect the revised update to the payment rates, as required by section 401 of BIPA.

- Replace the word "coinsurance" each time it appears in §§ 419.40, 419.41, 419.42 and 419.43 with the word "copayment."

- Redesignate existing § 419.41(c)(4)(ii) as paragraph (c)(4)(iv), and add paragraphs (c)(4)(ii) and (c)(4)(iii) to include the provisions of section 1833(t)(8)(C)(ii) of the Act. This section would specify that, effective for services furnished from April 1, 2001 through December 31, 2001, the national unadjusted coinsurance rate for an APC cannot exceed 57 percent of the prospective rate for that APC and the national unadjusted coinsurance rate for an APC cannot exceed 55 percent in calendar year 2004, 45 percent in calendar year 2005, and 40 percent in calendar year 2006 and thereafter.

- Revise § 419.70(d) to give children's hospitals the same permanent hold harmless protection as cancer hospitals under the OPPS, as required by section 405 of BIPA.

- Revise §489.24(i)(2)(ii) to clarify that, for the purposes of arranging an appropriate transfer of a patient

from an off-campus department, staff at the off-campus department may delay contacting the emergency personnel at the main hospital campus in the specific cases where doing otherwise would endanger a patient.

XII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Sections 413.65 and 419.42 of this proposed regulation contain information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995. However, §§413.65 and 419.42 have been approved by OMB under approval number 0938-0798, with a current expiration date of August 31, 2003 and OMB approval number 0938-0802, with a current expiration date of August 31, 2001.

XIII. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the **"DATES"** section of this preamble and respond to those comments in the preamble to that rule.

Modification of 60-day Comment Period

The highly complex analysis surrounding the possibility of a significant pro rata reduction has caused a delay in the publication of the proposed rule. It is essential for this rule to become effective by January 1, 2002 for hospital outpatient departments to receive appropriate higher payments and to ensure that beneficiaries receive the benefits of further reductions in beneficiary copayments.

Congress has directed us to update payment rates annually, at the beginning of each calendar year. If the increased provider payments and reduced beneficiary copayments do not become effective by the statutory effective date of January 1, 2002, enormous uncertainty and administrative difficulties will result for beneficiaries, providers, and intermediaries. In addition, any delay in receiving increased provider payments or reduced beneficiary copayments will cause harm to providers and beneficiaries. Consequently, in order to avoid imposing this uncertainty and harm on beneficiaries, providers, and intermediaries and to meet the January 1, 2002 statutory effective date for the update to the OPPS payment rates, we find we must shorten the comment period to 40 days. For the reasons discussed above, we find there is good cause to modify the 60-day comment period. We further find that this comment cycle will give parties sufficient opportunity to comment adequately on our proposed rule. In addition, we are immediately posting this proposed rule on our website at http://www.hcfa.gov/regs/cms1159p.htm pending publication in the **Federal Register** to ensure the maximum possible opportunity for public comment.